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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,059	12/29/2003	Kevor Tenhuisen	ETH-5119	8329

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EXAMINER

DORNBUSCH, DIANNE

ART UNIT	PAPER NUMBER
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3773

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/748,059

Applicant(s)

TENHUISEN ET AL.

Examiner

DIANNE DORNBUSCH

Art Unit

3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: ____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :03/15/2004, 04/07/2004, 06/30/2005.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claim 1-4, 6, and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Mikus et al. (2002/0151967).

Mikus discloses the following claimed limitations:

Claim 1: An apparatus for compressing a stent having at least one protrusion, comprising: a mandrel (114) insertable into a lumen of the stent (110) for holding the stent (Fig. 14); a protrusion compressor (115) coupled to said mandrel (114) (Fig. 4), said mandrel (114) rotatable relative to said protrusion compressor (115) ([0087] Lines 10-11), said protrusion compressor (115) having a tab (the hook in Fig. 14) extending therefrom towards said mandrel (114), said tab (the hook seen in Fig. 14 is pressing on one protrusion of the stent) pressing the at least one protrusion of the stent inwardly toward the lumen of the stent when said mandrel is rotated relative to said protrusion compressor ([0096] Lines 8-12 where as the rotation is making the stent expand it can also make it contract).

Claim 2: That said mandrel (114) extends through said protrusion compressor coaxially (Fig. 13-14).

Claim 3: That the apparatus further comprising a knob (117) disposed on an end of said mandrel (114) to aid in turning said mandrel (114) and for retaining said protrusion compressor (115) on said mandrel ([0096] Lines 9-10).

Claim 4: That said mandrel (114) has a stent fixation zone (112) with an outer diameter approximating the interior diameter of at least a portion of the lumen of the stent ([0089] Lines 1-5) and frictionally engaging the stent (110) when the stent (110) is placed on the mandrel (114) over the stent retention zone (112). The stent is placed on the mandrel where it has to have frictional engagement since both parts are touching each other as seen in Fig. 13.

Claim 6: That said protrusion compressor (115) is captured between said knob (117) and said stent retention zone (112) as seen in Fig. 14.

Claim 13: An apparatus for compressing a coiled stent (110) having at least one external protuberance, comprising: means for holding the stent (112 which is the stent segment, with gap/hook 127 of component 114 seen in Fig. 14); means for compressing (115) the at least one external protuberance (the hook seen in Fig. 14 is pressing on one protrusion of the stent), said means for compressing (115) being rotatably coupled to said means for holding (114) ([0087] Lines 10-11), such that relative rotation thereof compresses the at least one protuberance ([0096] Lines 8-12 where as the rotation is making the stent expand it can also make it contract), said means for compressing

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(115) acting on the stent by exerting a force (by using the hook in seen in Fig. 14) perpendicular to an axis of the stent (compresses it inwardly by pressing on it).

Claim 14: That the apparatus further comprising, means for gripping (117) said means for holding (114) the stent (110) to aid in rotating said means for holding relative to said means for compressing (115) ([0096] Lines 9-10).

Claim 15: The apparatus further comprising, means for gripping (118) said means for compressing the stent (115).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mikus et al. (2002/0151967).

Claim 5:

Mikus discloses the claimed invention except for that said mandrel has a tapered end. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Mikus with a tapered mandrel, since it has been held to be within the general skill of a worker in the art to taper the ends of the device to prevent unintentional damage to the worker while manufacturing the device as well as ease of construction of the device.

Claim 7:

Mikus discloses that said protrusion compressor (115) has a grip portion (the proximal end of 115 can be used to grip the device) with a hub (137) and a collar (118), and having said tab (the hook in Fig. 14) extending therefrom at a distal end thereof (Fig. 14). The hub (137) is used to lock the mandrel and the compressor longitudinally in relation to each other until longitudinal movement is desired. When movement is desired, the hub is easily removable, and is provided with a longitudinal slit to permit easy removal by the operator during surgery.

Mikus teaches all the claimed limitations discussed above however, Mikus does not disclose in this embodiment that the collar restrained from rotating relative to said grip portion by a pin extending there through and into an elongated slot in said hub.

Mikus in a second embodiment of the device discloses a pin (210, 236) that prevents movement ([0103] Lines 5-7) and that the pin is placed on a slit ([0106] Lines 8-9).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Mikus with a pin that restrict movement in view of the teachings of the second embodiment of Mikus, in order to prevent movement of the device that would cause the accidental deployment of the stent.

Furthermore, Mikus discloses the claimed invention except that said collar coaxially received on said hub instead of said hub (137) coaxially received on said collar (118) as seen in Fig. 14. This is an obvious rearrangement of parts therefore it would

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have been obvious to a person with ordinary skill in the art to switch the location of the collar and the hub since it is a matter of rearrangements of parts.

Claim 8: Mikus discloses that said collar (118) has a flange (extending portion in Fig. 14) extending outwardly therefrom for a user to grip said collar (118) to aid in deployment and retraction of said tab (Fig. 14 and [0087] Lines 14-15).

Claim 9: Mikus discloses that said grip portion (the proximal end of 115 can be used to grip the device) has a hollow post (114, the mandrel is an elongated shaft that extends throughout all the device) extending from said hub (137), said post (114) having a relief slot (123) on a distal end thereof (Fig. 13), said relief slot (123) positioned on said post (114) to align with said tab (the hook in Fig. 14) when said tab is in the deployed position. The mandrel and the protrusion compressor are rotatable with respect to each other, therefore when the post which is the mandrel (114) are in deploying position the hook and the relief slot will be align. Furthermore, Mikus discloses that said tab (the hook in Fig. 14) capturing the at least one protrusion of the stent, as seen in Fig. 14,, between said tab and said relief slot when said apparatus compresses the at least one protrusion (Fig. 14). Fig. 14 shows that the hook captures a piece of the stent which is between both the slot and the hook.

Claim 10:

Mikus discloses that the apparatus further includes a rotational inhibitor disposed between said grip portion (proximal end of 115) and said collar (118), said rotational inhibitor controlling the relative rotation ([0087] the last 5 lines). The rotational inhibitor can be different kinds of locking mechanisms such as a keyway structure.

Mikus teaches all the claimed limitations discussed above however, Mikus does not disclose the apparatus includes a ball and detent interface.

The ball and detent interface is well known in the art as a useful locking mechanism which can be use to inhibit the rotation of the device. Therefore it would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Mikus with a ball and recess mechanism in order to inhibit the rotation of the device as well as a locking mechanism to prevent a early deployment of the stent.

Claim 11: Mikus discloses different kinds of stents that can be used with the device.

One such stent is stent 10 which has the at least one protrusion of the stent (33 and 54) is at least one enlarged coil (33 and 54 in Fig. 8) disposed at an end of the stent (Fig. 8). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to add the coil (33 and 54) on stent 10 (and stent 110) in order to prevent the deployed stent in the urethra from obstructing the sphincter.

Claim 12: The apparatus further including a sleeve (116) extending from said collar (118) distal to said flange (Fig. 14), said tab (the hook in Fig. 14) extending from said sleeve (116). The tab extends from the sleeve as seen in Fig. 14 where it is distally from the distal end of the sleeve (116).

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The patents Bui et al. (6,413,269) and Thorud et al. (6,019,779),


all disclose a stent compressing and delivery system which retains the stent at a mandrel with a protrusion compressor.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANNE DORNBUSCH whose telephone number is (571)270-3515. The examiner can normally be reached on Monday through Thursday 7:30 am to 5:00 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. D./
Examiner, Art Unit 3773


(JACKIE) TAN-UYEN HO
SUPERVISORY PATENT EXAMINER